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| 10/676,263 | 10/02/2003 | Fumihisa Kitawaki | 43888-278 | 3473 |

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EXAMINER

VENCI, DAVID J

| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------------------|--|
| Office Action Summary | Application No. 10/676,263 | Applicant(s) KITAWAKI ET AL. | |
| | Examiner David J. Venci | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 16, 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 2, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicants' election of Group I, claims 1-10, without traverse, filed February 16, 2005. In addition, Applicants elect species, without traverse, from Category A - antibody, Category B - antigen, and Category C - protein.

Claims 11-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention, there being no allowable generic or linking claim.

Currently, claims 1-10 are under examination.

Specification

The disclosure is objected to because of the following informalities:

The first paragraph of 35 U.S.C. 112 requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with unclear and inexact terms and grammatical errors that render the specification indefinite. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. For example:

On p. 4, line 6, the phrase "been obstruction" is grammatically awkward.

On p. 5, lines 19, 21, 23 and 25, etc. the phrase "It is effective that..." is grammatically awkward and indefinite because the object of "it" is not known.

On p. 12, line 4, the phrase "those allow" is grammatically awkward.

On p. 25, lines 8-10, the phrase "this explanation", "the case", and "the drawings" is grammatically awkward and indefinite because the identity of "explanation", "case" and "drawings" is not clear.

On p. 5, line 21, p. 6, line 20, etc. the phrase "is acted" is grammatically awkward because the verb tenses do not agreed.

Appropriate correction is required.

The abstract of the disclosure is objected to because it does not concisely state that which is new in the art to which the invention pertains. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art. Correction is required. See MPEP § 608.01(b).

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show structural details described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Specifically, the drawings fail to show:

In Fig. 4:

“sampling element 2”, as described in the specification on p. 16, line 6

In Fig. 9:

“sampling element 1”, as described in the specification on p. 27, line 26; p. 28, lines 13 and 16

“handling device 40”, as described in the specification on p. 28, line 1; p. 28, line 14

“member 53”, as described in the specification on p. 28, line 4

“analyte 30”, as described in the specification on p. 28, line 12

“capillary tube 11”, as described in the specification on p. 28, line 13

“piston 43a”, as described in the specification on p. 28, lines 14 and 18

“syringe 43”, as described in the specification on p. 28, line 15

“reaction cell 46”, as described in the specification on p. 28, lines 15-16 and 18

“aluminum seal 44”, as described in the specification on p. 28, line 17

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"liquid 43b", as described in the specification on p. 28, line 18

The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(4) because different reference characters are used to designate the same structural details. For example:

reference characters "13" (Fig. 1) and "24" (Fig. 4) are both used to designate "adhesive tape"

reference characters "11" (Fig. 1) and "21" (Fig. 4) are both used to designate "capillary tube"

etc.

The drawings further are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference characters not mentioned in the description:

In Fig. 9, reference character 52 is not mentioned in the description.

In Fig. 12, reference character 76 is not mentioned in the description.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by

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the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation of "the outside" lacks antecedent basis. In addition, the recitation of "dynamic effect" lacks antecedent basis and is indefinite because a cause has not been recited. In addition, the recitation of "on which a dynamic effect is acted from" is grammatically awkward and is indefinite because the cause of said "dynamic effect" is not clear. It is not clear whether/how "the outside" causes said "dynamic effect." In addition, the recitation of "is acted" appears grammatically awkward because the verb tenses do not agree. In addition, the recitation of "is acted" is indefinite because it is not clear what entity is performing action.

Claim 1 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is a structural element(s) relating said "first region" to said "second region." It is not clear how a dynamic effect affecting said "second region" amounts to, or causes, a movement of said "first region."

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In claim 3, the recitation of "dynamic effect is acted on by change in magnetic field" is grammatically awkward and is indefinite because it is not clear whether/how a change in magnetic field acts on a dynamic effect. It is not clear whether a change in magnetic field causes a dynamic effect.

In claim 5, the recitation of "and/or" is indefinite because it is not clear whether verbiage subsequent to "and/or" contains required claim limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (US 6,632,399).

Kellogg et al. teach an analyte sampling element (see Abstract, "apparatus for performing microanalytic and microsynthetic analyses") comprising a first region capable of quantitatively collecting and temporarily retaining an analyte (see Fig. 9, metering capillary 702) and a second region (see col. 5, line 28, "rotors") on which a dynamic effect (see Abstract, "rotation") acts to move said first region.

With respect to claim 3, Kellogg et al. teach an analyte sampling element wherein a change in magnetic field (see col. 5, line 45, "centrifuges", col. 6, line 61, "electromechanical means") causes said dynamic effect (see Abstract, "rotation").

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With respect to claims 5-8, Kellogg et al. teach an analyte sampling element further comprising a reagent (see Table I, "Components on solid phase") for reacting with a substance (see Table I, "Assay for:"), and a reagent for destroying a cell (see Fig. 9, "lysis buffer chamber 716", col. 29, line 30, "0.1% Triton X100").

With respect to claims 9-10, Kellogg et al. teach an analyte sampling element wherein said cell is an erythrocyte (see col. 31, line 13, "lysed blood") and said component is hemoglobin (see col. 31, lines 47-50).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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04/04/05

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Examiner